

STATE OF MICHIGAN
DEPARTMENT OF LABOR & ECONOMIC GROWTH
OFFICE OF FINANCIAL AND INSURANCE REGULATION
Before the Commissioner of Financial and Insurance Regulation

XXXXX

Petitioner

File No. 100383-001

v

Priority Health HMO
Respondent

Issued and entered
this 30th day of December 2008
by Ken Ross
Commissioner

ORDER

I
PROCEDURAL BACKGROUND

On September 25, 2008, XXXXX (Petitioner) filed a request for external review with the Commissioner of Financial and Insurance Regulation under the Patient's Right to Independent Review Act, MCL 550.1901 *et seq.* On October 2, 2008, after a preliminary review of the material submitted, the Commissioner accepted the request for external review.

The case required analysis of medical issues. Pursuant to MCL 550.1911(6), the Commissioner assigned the matter to an independent review organization which submitted its recommendations to the Office of Financial and Insurance Regulation on October 15, 2008.

II
FACTUAL BACKGROUND

The Petitioner has been experiencing depression and fatigue. His primary care physician (PCP) prescribed hormonal therapy (testosterone in the form of Androgel) to treat these conditions. The Petitioner requested coverage and Priority Health denied the request.

The Petitioner appealed. After the Petitioner exhausted the internal grievance process, Priority Health issued a final adverse determination dated September 18, 2008.

III ISSUE

Did Priority Health properly deny coverage for Androgel?

IV ANALYSIS

Petitioner's Argument

Petitioner believes Androgel will help his depression and fatigue symptoms. He says he has exhausted all other therapies, including treatment with a psychiatrist for ten years and antidepressant medications, but his symptoms persist. His psychiatrist supports the PCP's recommendation for hormonal therapy. Priority Health denied the request for Androgel for treatment of Petitioner's depression and fatigue because his serum testosterone levels were within the normal range. However, Petitioner argues the question of what is normal, saying:

1. The question of what is "normal" is significant in this matter. The so-called normal range for testosterone levels is from 250-750. This is an extremely wide range, so much so that many patients may not fit this "normal range". The patient in this matter has twice tested in the very low 300's. What is really "normal" for this patient?
2. Much research has been done on the relationship of testosterone levels of males to depression and fatigue. Several research articles have been cited to the Priority Health Appeal Board. These articles included research with males whose testosterone levels ranged from 300 to 450. Even with these levels being in the "normal range". The research has concluded that hormonal therapy was beneficial to many of these patients.

The Petitioner believes Priority Health should provide coverage for the Androgel as prescribed by his physician because it is medically necessary to treat his condition.

Respondent's Argument

Priority Health denied coverage for the Androgel saying:

The use of prescription drug Androgel is not a covered benefit for patients with normal testosterone levels as outlined in the Priority Health Prior Authorization Form for Androgel which states the following:

FDA approved indication:

Replacement therapy in males for conditions associated with a deficiency

or absence of endogenous testosterone

Priority Health precertification requirements:

- Patient is male and over 18 years of age
- Laboratory confirmation of low testosterone levels for patient's naïve to testosterone and free testosterone levels

Note: A copy of laboratory results must be submitted documenting total testosterone and free testosterone level (normal levels vary between laboratories).

The FDA has approved use of Androgel for replacement therapy in males for conditions associated with a deficiency or absence of endogenous testosterone. However, since the Petitioner's testosterone levels are within normal range, Priority Health says Androgel is not medically necessary.

Priority Health further says that Androgel is not approved by the FDA for "off-label" use for treatment of depression and thus it would not be covered.

Priority Health believes that its benefit determination was appropriate.

Commissioner's Review

The Petitioner has pharmaceutical coverage as a benefit of his membership in Priority Health. Section 3406q of the Insurance Code, MCL 500.3406q, requires health maintenance organizations like Priority Health to provide coverage for "off-label" use of an FDA approved drug when certain conditions are met. "Off-label" means the use of a drug for clinical indications other than those stated in the labeling approved by the FDA. Section 3406q says:

(1) An expense-incurred hospital, medical, or surgical policy or certificate delivered, issued for delivery, or renewed in this state that provides pharmaceutical coverage and a health maintenance organization contract that provides pharmaceutical coverage shall provide coverage for an off-label use of a federal food and drug administration approved drug and the reasonable cost of supplies medically necessary to administer the drug.

(2) Coverage for a drug under subsection (1) applies if all of the following conditions are met:

(a) The drug is approved by the federal food and drug administration.

(b) The drug is prescribed by an allopathic or osteopathic physician for the treatment of either of the following:

(i) A life-threatening condition so long as the drug is medically necessary to treat that condition and the drug is on the plan formulary or accessible through the health plan's formulary procedures.

(ii) A chronic and seriously debilitating condition so long as the drug is medically necessary to treat that condition and the drug is on the plan formulary or accessible through the health plan's formulary procedures.

(c) The drug has been recognized for treatment for the condition for which it is prescribed by 1 of the following:

(i) The American medical association drug evaluations.

(ii) The American hospital formulary service drug information.

(iii) The United States pharmacopoeia dispensing information, volume 1, "drug information for the health care professional".

(iv) Two articles from major peer-reviewed medical journals that present data supporting the proposed off-label use or uses as generally safe and effective unless there is clear and convincing contradictory evidence presented in a major peer-reviewed medical journal.

(3) Upon request, the prescribing allopathic or osteopathic physician shall supply to the insurer or health maintenance organization documentation supporting compliance with subsection (2).

The Petitioner's PCP prescribed Androgel for depression and fatigue. The question of whether Androgel has been recognized for treatment of depression and fatigue was presented to an independent review organization (IRO). The IRO physician expert is board certified in internal medicine and has been in practice for more than 15 years. The IRO report said:

The MAXIMUS physician consultant explained that there is no documentation in the medical literature supporting the use of testosterone replacement therapy for symptoms of depression and fatigue in individuals with normal testosterone levels. The MAXIMUS physician consultant also explained that the literature clearly supports a connection between hypogonadism and improvement of depression after treatment with testosterone. However, the MAXIMUS physician consultant indicated that this member has normal testosterone and free testosterone levels. The MAXIMUS physician consultant also indicated that the [Petitioner] is under the care of a psychiatrist and is on medical therapy for his depression.

The MAXIMUS physician consultant explained that Androgel is not FDA approved for treatment of depression and fatigue in patients with normal testosterone levels. The MAXIMUS physician consultant also explained that Androgel is not being prescribed for a life-threatening condition or a chronic and serious debilitating condition for the [Petitioner]. The MAXIMUS physician consultant further explained that Androgel is not a recognized treatment for the condition for which it was prescribed in this case. Therefore, the MAXIMUS physician consultant concluded that the [Petitioner] does not meet the criteria for coverage of off-label use of Androgel as established by Michigan law.

The Commissioner is not required in all instances to accept the IRO's recommendation. However, the IRO recommendation is afforded deference by the Commissioner; in a decision to uphold or reverse an adverse determination the Commissioner must cite "the principal reason or reasons why the commissioner did not follow the assigned independent review organization's recommendation" MCL 550.1911(16)(b). The IRO's analysis is based on extensive expertise and professional judgment. The Commissioner can discern no reason why that judgment should be rejected in the present case. Therefore, the Commissioner accepts the conclusion of the IRO and finds that treatment of depression and fatigue is not an approved off-label use of Androgel in this case.

V ORDER

The Commissioner upholds Priority Health's September 18, 2008, final adverse determination.

This is a final decision of an administrative agency. Under MCL 550.1915, any person aggrieved by this Order may seek judicial review no later than sixty days from the date of this Order in the circuit court for the county where the covered person resides or in the circuit court of Ingham County. A copy of the petition for judicial review should be sent to the Commissioner of Financial and Insurance Regulation, Health Plans Division, Post Office Box 30220, Lansing, MI 48909-7720.